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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,222	03/23/2006	Daniel Raederstorff	22212USWO C038435/0196793	4962
7590	07/25/2007	Stephen M Haracz Bryan Cave 1290 Avenue of the Americas New York, NY 10104	EXAMINER	
ANDERSON, HEATHER L				
ART UNIT		PAPER NUMBER		
1655				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/573,222	RAEDERSTORFF ET AL.	
Examiner	Art Unit		
Heather Anderson	1655		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 18 June 2007.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-20 is/are pending in the application.
4a) Of the above claim(s) 1-13, 16, 19 and 20 is/are withdrawn from consideration.
5) Claim(s) _____ is/are allowed.
6) Claim(s) 14, 15, 18 and 78 is/are rejected.
7) Claim(s) _____ is/are objected to.
8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. ____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 03/23/2006.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) Notice of Informal Patent Application
6) Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election of Group III, a composition comprising a catechin and a PPAR γ ligand, in the reply filed on June 18, 2007 is acknowledged. Applicant's election of the specie ligustilide in the reply filed on June 18, 2007 is also acknowledged. It is noted that Applicant stated that both the election of an invention and a species was made with traverse, but because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-13, 16, 19 and 20 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention or species, there being no allowable generic or linking claim.

Claims 14-15 and 17-18 are presented for examination on the merits.

Specification

The disclosure is objected to because of the following informalities: typographical errors on page 1 ("individum" and placement of "(hereinafter: EGCG)" before epigallocatechin gallate) and page 4 (comma at the end of the paragraph on line 30).

Appropriate correction is required.

The use of the trademark TURRAX has been noted on page 13 in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

Claim 18 is objected to because of the following informalities: typographical error resulting because "14-17" was not crossed out when the claim was amended. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 14-15 and 17-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 10/525,348. Although the conflicting claims are not identical, they are not patentably distinct from each other because each are drawn to a composition comprising epigallocatechin gallate and the non-elected species phytanic acid.

Claims 14-15 and 17-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25-45 of copending Application No. 10/533,585 because each are drawn to a composition comprising epigallocatechin gallate and the non-elected species phytanic acid.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 14-15 and 17-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13 and 15-24 of copending Application No. 10/556,199 in view of Hara et al (US 5,318,986). Application No. 10/556,199 teaches a composition comprising ligustilide. This composition is used in withdrawn claims to treat diabetes. Hara et al. teaches the use of a composition comprising epigallocatechin gallate to treat diabetes. Therefore, it would have been obvious to one of skill in the art to combine the ligustilide of the '199 application with the

epigallocatechin gallate of Hara et al. to make a composition comprising ligustilide and epigallocatechin gallate.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14-15 and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Cui (CN 1120953, Derwent Abstract provided) with evidence provided by Ahmad et al. (Nutrition Reviews, March 1999) and Ko (Japanese Journal of Pharmacology, February 1980).*

A composition comprising a catechin found in green tea and peroxisome proliferators-activated receptor gamma (PPAR γ) ligand, specifically ligustilide, is claimed. Dependent claims include specifying the catechin as epigallocatechin gallate, a dosage of epigallocatechin gallate, and the composition to be a nutraceutical. It is noted that the specification defines nutraceutical on page 1, lines 19-20, such that the term "used herein denotes a usefulness in both the nutritional and pharmaceutical field of application."

Cui teaches a composition containing green tea (10-25%) and *Ligusticum wallichii* (5-12%) out of 5 total ingredients as a health-benefiting drink. Green tea is known to be an excellent source of catechins (as evidence - see, e.g., Ahmad et al., entire document including page 78, second column, last paragraph). Epigallocatechin gallate is the major catechin found in green tea, and one cup of green tea can contain up to 200 mg of epigallocatechin gallate (see page 79, first column, third paragraph). 10-25% of the composition taught by Cui contains green tea; therefore one cup of this composition would contain 20-50 mg of epigallocatechin gallate. *Ligusticum wallichii* is known to contain several phthalide compounds, one of which is ligustilide (as evidence - see, e.g., entire document including abstract of Ko); therefore the composition taught by Cui would inherently contain ligustilide.

Therefore the reference is deemed to anticipate the instant claims above.

* Please note that the Ahmad et al. and Ko references are not being cited as prior art within the 35 U.S.C. 102(b) rejection above but instead are being cited as evidence to show inherent properties of green tea and *Ligusticum wallichii* within the Cui composition.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 14-15 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cui (CN 1120953, Derwent Abstract provided) with evidence provided by Ahmad et al. (Nutrition Reviews, March 1999) and Ko (Japanese Journal of Pharmacology, February 1980).*

Cui beneficially teaches a composition comprising green tea (10-25%) and *Ligusticum wallichii* (5-12%) out of 5 total ingredients as a health-benefiting drink. Green tea is known to be an excellent source of catechins (as evidence - see, e.g., Ahmad et al., entire document including page 78, second column, last paragraph). Epigallocatechin gallate is the major catechin found in green tea, and one cup of green tea can contain up to 200 mg of epigallocatechin gallate (see page 79, first column, third paragraph). 10-25% of the composition taught by Cui contains green tea; therefore one

cup of this composition would contain 20-50 mg of epigallocatechin gallate. *Ligusticum wallichii* is known to contain several phthalide compounds, one of which is ligustilide (as evidence – see, e.g., entire document including abstract of Ko); therefore the composition taught by Cui would intrinsically contain ligustilide.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a health-benefiting beverage comprising the instantly claimed components of catechins found in green tea, such as epigallocatechin gallate, and ligustilide, found in *Ligusticum wallichii* based on the beneficial teachings of Cui. The adjustment of particular conventional working conditions (e.g., determining the amounts of green tea and *Ligusticum wallichii* and thus the amounts of epigallocatechin gallate and ligustilide respectively that would be health-benefiting) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

* Please note that the Ahmad et al. and Ko references are not being cited as prior art within the 35 U.S.C. 102(b) rejection above but instead are being cited as evidence to

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show inherent properties of green tea and *Ligusticum wallichii* within the Cui composition.

Conclusion

The prior art made of record and not relied upon that is considered pertinent to applicant's disclosure is as follows:

US 5,536,499 - a skin treatment composition comprising green tea and *Angelica* extract (see examples 10-12)

US 6,299,925 - green tea extract tablet including additional botanical components such as dong quai

JP 2003-235503 - a health food comprising green tea extract and *Angelica keiskei*

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather Anderson whose telephone number is (571) 270-3051. The examiner can normally be reached on Monday-Thursday, 7:30 AM-5:00 PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry KcKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

hla



CHRISTOPHER R. TATE
PRIMARY EXAMINER